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January 27, 2023

Honorable John Michael Vazquez, U.S.D.J.
U.S. District Court - District of New Jersey
Martin Luther King Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *In re Celgene Corp. Securities Litig.*, 18-cv-04772 (JMV) (JBC)

Dear Judge Vazquez:

We are co-counsel with Jones Day for Defendants in this action. Under Your Honor's Judicial Preferences, we seek to file a summary judgment motion on the securities fraud claims of Lead Plaintiff AMF Pensionsförsäkring AB ("AMF"), which relate to two Celgene drugs, Otezla and Ozanimod. Summary judgment is warranted in Defendants' favor on each of Lead Plaintiff's claims for several reasons, including but not limited to those summarized below, thus justifying a motion. A Statement of Undisputed Material Facts ("SUMF") is attached.

Otezla

Defendant Curran made the first alleged Otezla misstatement during Celgene's Q1 2017 earnings call on April 27, 2017. In response to an analyst's question asking if she "[c]an first walk through what gives you confidence [Otezla] growth will bounce back or could we see continued pressure in the near term," Curran stated as follows: "Importantly, if we look at the underlying dynamics of the business, they're exceptionally strong. If you look at the market share, OTEZLA continues to grow market share. We continue to gain more than 40% of new patients. And these new contracts will give us access to an additional pool of patients moving forward. Importantly, if we look at the exit run rates out of quarter 1 and into quarter 2, we do see the net sales rebounding and on track to deliver our 2017 guidance." SUMF ¶ 62.

The Court has ruled that Curran's statement "was a response to a question and constitutes [her] opinion on whether Otezla sales will bounce back." Dkt. 75 at 34. Accordingly, the statement is "only actionable under the securities laws" if it was "not honestly believed and lack[ed] a reasonable basis." *Id.* (quoting *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014)). Curran, however, testified that she believed the statement was true when she made it, SUMF ¶ 63, and there is no contrary evidence. Moreover, Lead Plaintiff cannot meet its burden of showing that Curran's opinion statement lacked a reasonable basis. Indeed, there is overwhelming evidence demonstrating that Curran had a reasonable basis for her statement. For example, in preparation for the April 27, 2017 earnings call, Curran emailed the Vice President of Finance, who was "primarily responsible for the financial strategy" of the business unit at issue ("I&I"), asking him "[h]ow do you go from the current run rate to \$1.5-\$1.7 billion for the full year?" He, in turn, consulted with the Senior Director, Global Business Planning and Development, and they advised Curran that "[w]hile the quarter was below our internal expectations, we exited the quarter with strong performance and trends in March and April that



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are consistent with the run-rate necessary to meet the full year guidance.” SUMF ¶ 55. Based on this and the other substantial evidence supporting Curran’s April 27, 2017 statement (*see, e.g.*, SUMF ¶¶ 45 - 56), Defendants are entitled to summary judgment on Lead Plaintiff’s claim to the extent it is based on that statement. Summary judgment in favor of Defendants is proper on other grounds, too, including Curran’s lack of scienter and the absence of loss causation.

Curran made the other alleged Otezla misstatement during Celgene’s Q2 2017 earnings call on July 27, 2017, when she said: “Q2 was an outstanding quarter for Celgene I&I, highlighted by significant sequential growth for OTEZLA. Key OTEZLA performance indicators continue to strengthen, and market share and prescriber adoption increased significantly in both U.S. and internationally.” SUMF ¶ 76. At the outset, the first portion of this statement, which refers to the “outstanding quarter” for Celgene’s I&I business unit generally, is an inactionable statement of optimism. *See, e.g., City of Edinburgh*, 754 F.3d at 172 (“vague and general statement[s] of optimism” like “spectacular” are not actionable). In any event, Otezla did experience “significant sequential growth” as net sales increased 48% in Q2 2017. SUMF ¶ 74. As for the remaining portion of her statement, regarding “[k]ey OTEZLA performance indicators” such as “market share and prescriber adoption,” Curran was referring to the charts that were presented during the earnings call at the time of her statement, which accurately showed, among other things, that Otezla’s psoriasis market share had increased from approximately 10% in January 2015 to 21.7% as of June 30, 2017 and that Otezla’s psoriasis “new-to-brand share” was 40.3% as of March 31, 2017. SUMF ¶¶ 77-79. At any rate, Curran’s statement was not knowingly or recklessly false or misleading when made. Additionally, because the sole alleged Otezla corrective disclosure provided that Celgene was lowering its 2017 Otezla net sales guidance for reasons unrelated to Otezla’s market share or prescriber adoption, that disclosure did not “reveal to the market the falsity” of Curran’s statement about those two metrics, which precludes a finding of loss causation. *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 175 n.4 (2d Cir. 2005).

Ozanimod

AMF first contends that Smith’s April 27, 2017 statement that Celgene “would submit [the] Ozanimod NDA ... in 2017” was misleading because Smith failed to disclose the existence of a previously undiscovered metabolite that Celgene supposedly knew would result in the FDA issuing a refusal to file (“RTF”) denying the complete review of the NDA. But Celgene did submit the Ozanimod NDA in 2017, and the uncontroverted evidence shows that Celgene had not yet discovered the metabolite at the time of Smith’s statement. It was not until months later that Celgene confirmed the metabolite’s existence. SUMF ¶ 112. Smith’s April 27, 2017 statement was thus neither misleading nor made with the requisite scienter.

Smith’s statements on July 27, 2017, that he felt “very, very good about the data emerging and look[ed] forward to getting it out,” that Ozanimod had “positive-top line data in RMS,” and that it was “advancing towards FDA filing YE:17” were likewise not misleading, let alone knowingly or recklessly so, for failing to disclose the metabolite’s existence. Two days earlier, Smith was advised that a new metabolite had been identified but that several Celgene consultants who were former FDA officials (from the “tox[icology], clin[ical] pharm[acology] and division director



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level”) and who were advising Celgene about the NDA all “indicate[d] that [Celgene’s] plan/data [regarding the new metabolite] should be acceptable to the agency and allow [Celgene] to keep the submission on schedule.” SUMF ¶ 126. Smith was also informed that “approvability is not impacted by this new finding.” *Id.* There is no evidence Smith was told anything to the contrary about the metabolite prior to his statements on July 27, 2017.

The remaining alleged Ozanimod misstatements made by individual Defendants are Smith’s and Defendant Martin’s October 2017 statements that “ozanimod FDA filing in RMS by YE:17 [would be] an inflection point in 2017 that would drive growth for Celgene”; that Celgene “is tremendously thrilled with [positive data in Phase III studies]”; and that the Phase III studies would “form the basis of [Celgene’s] submission to the FDA,” which Celgene was “working hard to file by the end of the year.” But those studies *did* “form the [NDA’s] basis,” which Celgene *was* “working hard” to submit—and *did* submit—“by the end of the year.” Nor did Smith or Martin make those statements with the requisite scienter. Celgene still had a plan approved by ex-FDA consultants to address the metabolite, and the FDA did not provide Celgene with any feedback on that plan until November 21, 2017, after Defendants Smith and Martin made the alleged misstatements. SUMF ¶ 148. Moreover, there is no evidence that Smith or Martin (nor any other Celgene employee for that matter) thought that the metabolite was likely to lead to an RTF.

AMF also seeks to rely on the doctrine of corporate scienter to hold Celgene liable for alleged misstatements not made by any of the individual Defendants. But as this Court has cautioned, that doctrine, if it is even viable in the Third Circuit, applies “only ... in unique and extraordinary circumstances” involving “blatantly false statements” or “widespread and egregious corporate fraud” akin to “General Motors announc[ing] that it had sold one million SUVs ... and the actual number was zero.” Schwab MTD Op. at 18-20. Neither is remotely present here. The statements at issue were literally true, and thus could not have been “blatantly false.” And the record and common sense refute any suggestion that Celgene engaged in a “widespread and egregious” fraud to submit an NDA that it knew would immediately be rejected by the FDA. Nor can AMF show that Smith “made” any of these statements pursuant to *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135 (2011), or that he had scienter in any event.

Finally, Defendants are also entitled to summary judgment because Lead Plaintiff cannot establish loss causation for any stock price decline following Morgan Stanley’s April 29, 2018 report. Morgan Stanley’s opinion that Celgene would “likely need to re-run preclinical toxicology which could take 6 months (rats) to 2 years (another carcinogenicity study)” was unreasonable and wholly incorrect; indeed Morgan Stanley walked back its analysis just days later, and Celgene did not have to rerun any such studies. SUMF ¶¶ 168-170.

/s/ Lawrence S. Lustberg
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cc: All Counsel of Record (via e-mail)